

Food Safety and Inspection Service

Washington, D.C. 20250

Dr. Halldor Runolfsson Chief Veterinary Officer Ministry of Agriculture Solvholgata 7 150 Reykjavik, Iceland

EEB 0 1 2005

Dear Dr. Runolfsson:

This letter transmits the Food Safety and Inspection Service's final report of a meat inspection system audit conducted in Iceland September 13 through September 22, 2004. A copy of this report is enclosed for your records.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White, Director

International Equivalence Staff

Sally White JD

Office of International Affairs

Enclosure

cc:

Roger Wentzel, Agricultural Counselor, US Embassy, The Hague, Netherlands Borghildur Magnusdottir, FAS, US Embassy, Reykjavík, Iceland David Jaberg, Economic/Commercial Officer, US Embassy, Reykjavík Gudni Bragason, Deputy Chief of Mission, Embassy of Iceland, Washington, DC Scott Bleggi, FAS Area Officer Amy Winton, State Department Karen Stuck, Assistant Administrator, OIA, FSIS Bill James, Deputy Assistant Administrator, OIA, FSIS Linda Swacina, Executive Director, FSIA, OIA, FSIS Donald Smart, Director, Program Review, OPEER, FSIS Sally White, Director, ES, OIA, FSIS Clark Danford, Director, IEPS, OIA, FSIS Armia Tawadrous, Director, FSIS CODEX Staff, FSIS Mary Stanley, Director, IID, FSIS Todd Furey, IES, OIA, FSIS Nancy Goodwin, IES, OIA, FSIS Country File (FY 2004 Audit)

FINAL

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FINAL REPORT OF AN ENFORCEMENT AUDIT CARRIED OUT IN ICELAND COVERING ICELAND'S MEAT INSPECTION SYSTEM

SEPTEMBER 15 THROUGH 24, 2004

Food Safety and Inspection Service United States Department of Agriculture

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2

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA Central Competent Authority [Ministry of Agriculture, Chief

Veterinary Office]

DVO District Veterinary Officer

E. coli Escherichia coli

FSIS Food Safety and Inspection Service

PR/HACCP Pathogen Reduction / Hazard Analysis and Critical Control Point

Systems

Salmonella Salmonella species

SSOP Sanitation Standard Operating Procedures

Iceland September 2004

1. INTRODUCTION

The audit took place in Iceland from September 15 through 24, 2004.

An opening meeting was held on September 15, 2004 in Reykjavik, Iceland with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and scope of the audit, the auditors' itinerary, and requested additional information needed to complete the audit of Iceland's meat inspection system.

The auditors were accompanied during the entire audit by a representative from the CCA and a representative from the regional and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was an enforcement audit. The objective of the audit was to determine whether Iceland could continue to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, three district offices, and three slaughter and processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	District	3	
Slaughter and Processing Establishments		3	

3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or regional offices. The third part involved on-site visits to three slaughter and processing establishments.

Program effectiveness determinations of Iceland's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for generic E. coli, (4) residue controls, and (5) enforcement controls, including a testing program for Salmonella. Iceland's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by Iceland and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

During the opening meeting, the auditors explained that Iceland's inspection system would be audited against two standards. First, the auditors would audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and FSIS' requirements for HACCP, SSOP, testing for generic E. Coli.

Second, the auditors would audit against any equivalence determinations that have been made by FSIS for Iceland under provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures.

Iceland is permitted to slaughter equines in the same establishment as lambs.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at: http://www.fsis.usda.gov/regulations/foreign_audit_reports/index.asp

The following concerns arose as a result of the FSIS audit of Iceland's inspection system conducted in September 2003:

Government Oversight: Control and Supervision

- Communications between the central headquarters offices and the District Veterinary Officers were not uniform.
- In three of the four establishments, there were deficiencies in inspection controls regarding enforcement of FSIS requirements.

Government Oversight: Assignment of Inspectors

- In one establishment, the Veterinarian-In-Charge did not have a clear understanding of FSIS requirements.
- In two establishments, the Veterinarians-In-Charge had had no specific HACCP training.

Government Oversight: Enforcement of US Requirements

- In one establishment, HACCP- and SSOP- implementation deficiencies resulted in a Notice of Intent to Delist.
- One establishment was delisted for failure to meet U.S. requirements.
- These deficiencies should have been identified by the Ministry of Agriculture before this FSIS audit, and regulatory enforcement actions should have been taken.

Sanitation Controls

SSOP

- In two of the four establishments audited, Sanitation Standard Operating Procedures (SSOP) were not effectively implemented.
- In one establishment, documentation of pre-operational and operational sanitation conditions did not reflect the actual conditions observed throughout the establishment during the audit
- In one establishment, documentation by establishment personnel of preventive measures in response to pre-operational and operational deficiencies was inadequate. This was a repeat finding in this establishment.
- In one establishment, the dropped-meat reconditioning procedure was not included in the written SSOP as required.

Sanitation Performance Standards

- In two establishments, maintenance and cleaning of over-product structures had been neglected to varying degrees.
- In three establishments, light intensity at inspection stations was inadequate.
- In one establishment, fecal contamination was found on a carcass in one lamb cooler. This was a repeat finding, in this establishment.
- In one establishment, an employee was not sterilizing his knife, as required, after contaminating it, before continuing to use it for carcass trimming.
- In one establishment, insanitary storage of exposed product was observed.
- In one establishment, there was inadequate cleaning of product-contact equipment before the start of operations.
- In one establishment, insanitary storage of product-contact equipment and materials was found.
- In one establishment, personal hygiene deficiencies were observed.
- In one establishment, large, unmarked containers of chemicals were found in the main chemical store.
- In one establishment, there was inadequate separation of work and street clothing.

Slaughter Processing Controls

- HACCP Implementation
 - In two of the four establishments, the U.S. HACCP requirements had not been effectively implemented.
 - In one establishment, verification procedures were not included in the written HACCP plan.
 - In one establishment, the description of the monitoring procedure in the written HACCP plan was inadequate. It did not include either the frequency of the monitoring of the CCP or the number of carcasses to be monitored.
 - In one establishment, the HACCP implementation deficiency (in addition to SSOP deficiencies) was sufficient to warrant the issuance of a Notice of Intent to Delist if the problems were not corrected within 30 days.
 - In one establishment, there were some verification activities for the monitoring of critical limits, but the written description of these procedures was vague, and the documentation of the verification was inadequate.
- Testing for generic E. coli
 - In one establishment, a statistical process control program had not been developed, as required, to evaluate the results of the testing for generic E. coli.

Residue Controls

- In the residue laboratory audited, there was no written corrective action program for instances in which an analyst's proficiency does not meet expectations.
- Also, in the same laboratory, several illegible corrections were observed in recent entries in the standards books.

Enforcement Controls

- In three of the four establishments, deficiencies were found that should have been identified and addressed by the Ministry of Agriculture prior to this audit by FSIS.
- In one establishment, the Veterinarian-In-Charge was unable to provide any documentation of his pre-operational sanitation inspections.
- In two establishments, the Veterinarians-In-Charge were not documenting any evaluation of establishment compliance with FSIS requirements regarding the implementation of SSOP or HACCP procedures.
- In one establishment, the Veterinarian-In-Charge had noted insufficient light in the reinspection area of the main lamb cooler, but no target date had been set for correction.
- In one establishment, inedible product was not controlled adequately.

MAIN FINDINGS

6.1 Legislation

The auditors were provided a copy of the Regulation on the slaughtering and the handling of slaughterhouse products.

6.2 Government Oversight

6.2.1 CCA Control Systems

The Act on Veterinarians and Animal Health Services, No. 66/1998, outlines the organization of the fourteen veterinary districts. The fourteen District Veterinarians are under the supervision of the Ministry of Agriculture, Chief Veterinary Office.

The staffing within these districts is as follows: In one of the establishments, the District Veterinarian has a staff of one Veterinarian in Charge of the establishment with two assistants. In the other two establishments, the District Veterinarian is the Veterinarian in Charge in the establishment. Each of these veterinarians also has two assistants.

6.2.2 Ultimate Control and Supervision

The Act on Veterinarians and Animal Health Services, No. 66/1998, states that the responsibilities of the Chief Veterinary Officer include the management and monitoring of the work of district veterinarians, veterinary specialists, and other veterinarians having permits to work as (practicing) veterinarians.

6.2.3 Assignment of Competent, Qualified Inspectors

The Chief Veterinary Office arranged two training sessions for their employees since the last audit. The first took place in November 2003. During this session, the focus of the discussions was on PR/HACCP, SSOP and FSIS Directive 5000.1, Rev. 1. The second course took place in June 2004. The focus of this class was on how to conduct an audit of a meat inspection system.

6.2.4 Authority and Responsibility to Enforce the Laws

The Act on Veterinarians and Animal Health Services, No. 66/1998, provides the Chief Veterinary Office with explicit authority over animal health matters and hygiene.

6.2.5 Adequate Administrative and Technical Support

Iceland's Ministry of Agriculture has adequate administrative and technical support and has the ability to support a third party audit.

6.3 Audit of Headquarters and Local Offices

The auditors conducted a review of inspection system documents at the headquarters of the inspection service and in three district offices. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sanitation, slaughter and processing inspection procedures and standards.
- · Export product inspection and control including export certificates.

No concerns arose as a result of the examination of these documents.

7. ESTABLISHMENT AUDITS

The FSIS auditors visited a total of three establishments. All three were combined slaughter and processing establishments. No establishments were delisted or received a Notice of Intent to Delist.

8. SANITATION CONTROLS

As stated earlier, the FSIS auditors focused on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Iceland's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene and practices, and good product handling and storage practices.

In addition, and except as noted below, Iceland's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

8.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program. The SSOP in three establishments were found to meet the basic FSIS regulatory requirements. However, one deficiency was noted:

 In one establishment, the knife sanitizer in the slaughter area had lamb wool leftover from previous day's operation.

8.2 Other Sanitation Deficiencies

- In one establishment, three light fixtures in the deboning room had dust accumulation.
- In one establishment, pieces of fat were found on the overhead structures in the slaughter area.

9. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Iceland's inspection system had adequate controls in place. No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

10. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic E. coli in slaughter establishments.

10.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

10.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

 The HACCP programs were reviewed during the on-site audits of the three establishments. It was found that these establishments had adequately implemented the HACCP requirements.

10.3 Testing for Generic E. coli

No deficiencies were noted.

10.4 Testing for Listeria monocytogenes

Iceland does not export ready to eat product, therefore the requirements for testing for Listeria monocytogenes do not apply.

11. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

No deficiencies were noted.

12. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for Salmonella.

12.1 Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments.

12.2 Testing for Salmonella

FSIS does not require testing for Salmonella species in lambs.

12.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

12.4 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required.

12.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market. In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing.

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

13. CLOSING MEETING

A closing meeting was held on September 24, 2004 in Reykjavik, Iceland with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Todd M. Furey USDA, FSIS, OIA

14. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report (when it becomes available)

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AJD.T DATE	2 AUDIT DATE 3. EST		ESTABLISHMENTING. 4. NAME OF COUNTRY		
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7. Written SSOP		33.	Scheduled Sample			
Records documenting implementation.		34.	Species Testing			
9. Signed and dated SSCP, by on-site or overall authority.		35.	Residue		1 - 1 - 1	
Sanitation Standard Operating Procedures (St Ongoing Requirements	SOP)		Part E -	Other Requirements		
10. Implementation of SSOP's, including monitoring of imp	elementation.	36.	Export			
11. Maintenance and evaluation of the effectiveness of SS	OP's	37	Import			
 Conective action when the SSOPs have failed to preven product contemination or aduteration. 	ent direct	38.	Establishment Grounds	and Pest Control		
13. Daily records document item 10, 11 and 12 above.		39.	Establishment Construc	tion/Maintenance		
Part B - Hazard Analysis and Critical Contro Point (HACCP) Systems - Basic Requiremen		40.	Light		= -	
14. Developed and implemented a written HACCP plan.		41.	Ventilation			
 Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, correct 	ive actions.	42.	Plumbing and Sewage			
 Records documenting implementation and monitoring HACCP plan. 	of the		Water Supply			
 The HACCP plan is aigned and dated by the responsible establishment individual. 	onsible		Dressing Rooms/Laveto			
Hazard Analysis and Critical Control Point						
(HACCP) Systems - Ongoing Requirements		46.	Sanitary Operations			
18. Monitoring of HACCP plan.		47.	Employee Hygiene			
19. Verification and validation of HACCP plan.		48	Condemned Product Co	ntrol		
20. Corrective action written in HACCP plan.	r con		120000000000000000000000000000000000000		_	
21. Resessed adequacy of the HACCP plan.			Part F - In	spection Requirements		
 Records documenting: the written HACCP plan, monte critical control points, dates and times of specific even 	oring of the t occurrences	49.	Government Staffing			
Part C - Economic / Wholesomeness		50.	Daily Inspection Coverag	24	1	
23. Labeling - Product Standards		51	Enforcement	-1111	7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	
24. Labeling - Net Weights	1	-			1	
25. General Labeling		52.	Humane Handling			
28 Fin. Prod. Standards/Boneless (Defects/AQU/Pork Skins/Moisture) Part D - Sampling Generic E. coll Testing		53.	Animal identification			
		54.	Ante Mortem Inspection			
27. Written Procedures		55.	Post Mortem Inspection			
28. Sample Collection/Analysis						
29. Records			Part G - Other Regul	latory Oversight Requirements		
Salmonella Performance Standards - Basic Ro	equirements	56.	European Community Dir	ectives	0	
30. Conscive Actions	0	57.	Monthly Review			
31. Reassesament	0	58.				
32. Written Assurance	0	đĐ.				

80. Observation of the Establishment

Ideland Est. 22 Slaughter Processing

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

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Part A - Sanitation Standard Operating Procedure Basic Requirements	es (SSOP) Audi Results	Part D - Continued Economic Sampling	Audit Results		
7. Written SSOP		33. Scheduled Sample			
8. Records documenting implementation.	10.000	34. Species Testing			
9. Signed and dized SSOP, by on-site or overall authority.		35. Residue			
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10. Implementation of SSOP's, including monitoring of imple	mentation.	38 Export			
11. Maintenance and evaluation of the effectiveness of SSO	P's. X	37. Import			
 Corrective action when the SSOPs have failed to prever product contamination or aduteration. 	nt direct	38. Establishment Grounds and Pest Control			
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance			
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21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements			
Records documenting: the written HACCP plan, monitori pritical control points, dates and times of specific event.	ing of the	49. Government Staffing			
Part C - Economic / Wholesomeness	-	50. Daily Inspection Coverage			
23. Labeling - Product Standards					
24. Labeling - Net Weights		S1. Enforcement			
25. General Labeling		52. Humane Handling			
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins	Moisture)	53. Animal Identification			
Part D - Sampling Generic E. coli Testing		54. Ante Mortem Inspection			
27. Written Procedures	IVERTONIA I	55. Post Mortem Inspection			
9. Sample Collection/Analysis					
29. Repords		Part G - Other Regulatory Oversight Requirements	+		
Salmonella Performance Standards - Basic Requirements		86. European Community Directives O			
30. Corrective Actions	0	57. Monthly Review			
31. Reessessmert	0	52.			

- 60. Observation of the Establishment
- Iceland Est. 31 Slaughter Processing
- 11 = Evisceration Department. Pieces of Lamb wool was found in 3 knives sanitizers during pre-op-sanitation. (9 CFR 416.13)
- 40 = Deboning Department. The dust accumulation was observed in 3 light fixtures during pre-op-sanitation. (9 CFR 416.4)
- 45 = Evisceration Department. Meat pieces were observed on the overhead rail during pre-op-sanitation. (9 CFR 416.4)

62 AUDITOR SIGNATURE AND DATE

09/27/2004

United States Department of Agriculture Food Safety and inspection Service

Foreign Establishment Audit Checklist

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60 Cosemistion of the Establishment

Iceland Est. = 81. Slaughter Processing

62 AUDITOR SIGNATURE AND DATE





EMBÆTTI YFIRDÝRALÆKNIS

USDA, FSIS International Equivalence Staff Office of International Affairs Dr. Sally White, director

1400 Independance Ave Washington DC. USA Sölvhólsgata 7 - 150 Reykjavík Sími: 545 9750, bréfasími 552 1160 kt 660169-5399 www.yfirdyralaeknir.is

Rundfron

Reykjavík, 15. janúar 2005 Tilvísun: YDL04060012/511 HR/söh

The Chief Veterinary Officer has on November 30th 2004 received your letter dated Nov 17 2004 where FSIS invited us to provide comments regarding the information in the report on your on - site audit of Iceland's meat inspection system conducted from September 15 through September 29, 2004.

We have studied the report and have no comments on the factual information contained therein.

Sincerely yours

Halldór Runólfsson Chief Veterinary Officer

CC: American Embassy Reykjavik, Iceland Ministry for Foreign Affairs, Reykjavík, Iceland